



Food and Drug Administration
Rockville MD 20857

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Julian M. Whitaker, M.D.
Emord & Associates
5282 Lyngate Court
Burke, VA 22015

Docket Nos. 02P-0243/CP1 and
02P-0244/CP1

Dear Dr. Whitaker:

This letter responds to your citizen petitions dated May 24, 2002, requesting that the Food and Drug Administration (FDA) issue a Medication Guide defining the adverse health effects of statin drugs, including statin-induced deficiency of coenzyme Q10 depletion, and require a boxed warning in the labeling regarding the need to take supplemental coenzyme Q with statin drugs.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible, given the numerous demands on the Agency's resources.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

02P-0243

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